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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/747,702

12/30/2003

Sultan Ahmad

ASZN0039-101
(A1807-2P US

2881

7590

05/31/2006

EXAMINER

LI, RUIXIANG

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ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/747,702

Applicant(s)

AHMAD ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-67 is/are pending in the application.
- 4a) Of the above claim(s) 48-67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43, 44 and 46 is/are allowed.
- 6) ☒ Claim(s) 45 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 05/17/2006 has been entered in full. Claims 1-42 have been canceled. Claims 43-67 have been added and are pending. Claims 43-47 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 6, 7, and 41 under 35 U.S.C. §112, 2nd paragraph, as set forth in the previous office action, has been made moot by canceled claims.

The objection to the title set forth in previous office action is withdrawn in view of the amended title.

Claim Rejections under 35 U.S.C. §112, 2nd paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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(ii). Claims 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substantially pure protein comprising SEQ ID NO: 3, does not reasonably provide enablement for a substantially pure protein variant of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 45 is drawn to a substantially pure protein comprising SEQ ID NO: 3 and further comprising amino acid additions, deletions, or substitutions in SEQ ID NO: 3 that do not substantially alter the binding properties of the protein, whereas claim 47 is drawn to a composition comprising the protein of claim 45. The claims do not recite any structural limitations for the protein variant. While the claims recite "the binding properties of the protein", such a limitation does not define a specific biological activity because it does not clearly point out what binding property is referred. Thus, the claims are broad.

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The specification fails to provide sufficient directions and/ or working example on how to make and use the claimed variants of protein of SEQ ID NO: 3. While disclosing a radioligand assay for receptor binding (page 12), the instant specification does not disclose a single ligand that binds the instantly claimed dorsal root receptor protein of SEQ ID NO: 3. The prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to make and use the instantly claimed protein variants. One would have first to screen a ligand for the dorsal root receptor protein of SEQ ID NO: 3 before making and using a variant of the protein of SEQ ID NO: 3. It is unpredictable which compound would act as a ligand and binds the dorsal root receptor protein of SEQ ID NO: 3 because the specification does not provide any structural features of the ligand. Accordingly, it would take undue experimentation for one skilled in the art to make and use the genus of the variants of the protein of SEQ ID NO: 3.

Claim Rejections under 35 U.S.C. §112, 2nd paragraph

Claims 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is indefinite because it recites "...comprising SEQ ID NO: 3 and further comprising amino acid additions, deletions, or substitutions in SEQ ID NO: 3...". It is unclear what the metes and bounds of the limitations are. Moreover, the claim also

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recites "the binding properties of the protein". It is not clear what binding property and "the protein" are referred to. Claim 47 is rejected as a dependent claim.

Conclusion

Claims 43, 44, and 46 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

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The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
May 27, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER